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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,932	04/05/2004	Jonathan Schneck	001107.00466	7013

22907 7590 08/08/2005

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WASHINGTON, DC 20001

EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 08/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/816,932

Applicant(s)

SCHNECK ET AL.

Examiner

DiBrino Marianne

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 21-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 21-52 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment filed 4/14/04 is acknowledged and has been entered.
2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 21-23, drawn to a composition comprising a cell with a chimeric protein bound thereto, classified in Class 424, subclass 93.7.

II. Claims 24-40, drawn to a method of treatment of allergy, transplantation rejection, autoimmunity, cancer or infection comprising administering a chimeric protein, classified in Class 424, subclasses 193.1 and 178.1.

III. Claims 41-52, drawn to a method of labeling antigen specific T cells comprising contacting a sample comprising antigen specific T cells with a chimeric protein, classified in Class 424, subclass 193.1 and Class 435, subclass 7.24.

3. Inventions II and III are different methods of use.

These inventions require different ingredients and process steps to accomplish the use of treating a disease or condition by administering the chimeric protein to a subject (Invention I), or of labeling antigen specific T cells *in vitro* using the chimeric protein or *in vivo* using the chimeric protein (Invention II).

4. Inventions II and Inventions I and III are not related as product and a method of use. Therefore, they are novel and unobvious in view of each other and are patentably distinct.

5. Because these inventions are distinct for the reasons given above and the search required for any group from Groups I-III is not required for any other group from Groups I-III and Groups I-III have acquired a separate status in the art as shown by their different classification and divergent subject matter, restriction for examination purposes as indicated is proper.

6. **If Applicant elects Invention I**, Applicant is further required to (1) elect a single disclosed species of composition comprising a specific cell bound to a specific chimeric protein (for example, a dendritic cell bound to a chimeric protein comprising an MHC molecule that is HLA-A2  $\alpha 1$ ,  $\alpha 2$  and  $\alpha 3$  regions and  $\beta 2m$  and further comprising an immunoglobulin chain that is the variable region of IgG1, wherein the influenza A M158-166 peptide is bound to the MHC molecule) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

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7. **If Applicant elects Invention II**, Applicant is further required to (1) elect a single disclosed species of chimeric protein to be used in the claimed method of treatment **and** a specific condition to be treated (for example, a chimeric protein comprising an MHC molecule that is HLA-A2  $\alpha 1$ ,  $\alpha 2$  and  $\alpha 3$  regions and  $\beta 2m$  and further comprising an immunoglobulin chain that is the variable region of IgG1, wherein the influenza A M158-166 peptide is bound to the MHC molecule, and treating a viral infection) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different, and the conditions are different conditions to be treated having different etiologies.

8. **If Applicant elects Invention III**, Applicant is further required to (1) elect a single disclosed species of chimeric protein to be used in the claimed method of labeling antigen specific T cells **and** if the contacting step is performed *in vivo* or *in vitro* **and** if the method comprises a step for detecting a marker for activation of antigen specific T cells elect a specific marker for activation (for example, a chimeric protein comprising an MHC molecule that is HLA-A2  $\alpha 1$ ,  $\alpha 2$  and  $\alpha 3$  regions and  $\beta 2m$  and further comprising an immunoglobulin chain that is the variable region of IgG1, wherein the influenza A M158-166 peptide is bound to the MHC molecule, and wherein the contacting step is performed *in vitro*, and wherein the method further comprises detecting a marker for activation of antigen specific T cells that is a secreted lymphokine) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

These species are distinct because their structures are different.

9. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

10. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

11. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

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12. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

15. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Marianne DiBrino*

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July 29, 2005

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